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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/820,590      | 04/08/2004  | Paul Albert Sage1    | 9031R               | 8118             |

27752 7590 08/22/2007  
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CINCINNATI, OH 45224

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| EXAMINER |
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ROBERTS, LEZAH

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| ART UNIT | PAPER NUMBER |
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1614

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| MAIL DATE | DELIVERY MODE |
|-----------|---------------|

08/22/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/820,590 | <b>Applicant(s)</b><br>SAGEL ET AL. |  |
|                              | <b>Examiner</b><br>Lezah W. Roberts  | <b>Art Unit</b><br>1614             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-16 is/are pending in the application.
- 4a) Of the above claim(s) 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

This Office Action is in response to the Request for Continued Examination filed May 25, 2007. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Claims*

#### **Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)**

1) Claims 1-3, 5-8 and 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godbey et al (US 2002/0187181) in view of Sagel et al. (US 5,891,453).

Godbey et al. disclose delivery systems comprising a water-soluble polymeric carrier, an adhesive, one or more active agents and a support layer. The active agent includes whitening agents such as hydrogen peroxide (paragraph 0051) and may be incorporated into either one or both of the carrier and the adhesive compositions (paragraph 0008). When the active agent is in both the adhesive and carrier, the combination of the two may be considered one composition. The polymers that may be used as carriers include cold water-soluble polymers such as polyvinyl alcohol, which is the one of the preferred polymers, polyoxyalkylenes, which may include polyethylene oxide, and mixtures thereof. The advantage of using polymers of polyvinyl alcohols to prepare the carrier film is that the film may, as a result of its low oxygen permeability,

Art Unit: 1614

provide protection to oxygen sensitive materials (paragraph 0025). The polyvinyl alcohol used in the examples was 87% hydrolyzed, encompassing claim 7, and may comprise 30 to 35% of the compositions. Plasticizers that may be used include polyethylene glycol, water and mixtures and comprise from 1 to 50% of the carrier. Plasticizers are used to form films with reduced brittleness. The adhesive compositions also include cold water-soluble polymers, such as poly(ethylene oxide) (paragraph 0036), and the polymers may be an uncross-linked polymer or mixture of polymers with an overall number average molecular weight between 10,000 and 100,000 Daltons. Such polymers provide a good balance of cohesive strength and water-solubility. The adhesive polymer comprises about 10 to about 60 weight percent of the adhesive composition, encompassing claim 2. Plasticizers comprise up to 80% of the adhesive compositions. The amount of water used in the adhesive compositions comprises up to 60% of the adhesive (paragraph 0041). This limitation encompasses the instant claims whether the whitening composition is the adhesive layer or the combination of the adhesive layer and carrier. It can be concluded that up to 60% water and amount of plasticizer is in the final product and not just the initial mixture because the components were disclosed as being in the compositions and not only being indicated as being used to make the compositions. Both the adhesive and the carrier compositions use cold water-soluble polymers, therefore it may be concluded that the polymers disclosed for the adhesive compositions may be used in the carrier compositions and vice versa, therefore a mixture of polyvinyl alcohol and polyethylene oxide is encompassed by the reference. Even if it is not the case that polyoxyethylene is not among polymers that

Art Unit: 1614

may be used in the carrier or polyvinyl alcohol is not one of the polymers that may be used in the adhesive layer, the adhesive composition and the carrier compositions may be considered one whitening composition comprising two polymers just in two different layers because they both may contain the whitening active, as stated above in this section. The support layer may be a multilayered laminate (paragraph 0057), encompassing claim 8.

The reference differs from the instant claims insofar as it does not disclose the teeth whitening devices were packaged and the amount of whitening compositions comprised on the support layer.

Sagel et al. disclose systems for delivering whitening substances. The systems comprise strips coated with a whitening composition or substance. The compositions comprise whitening agents such as hydrogen peroxide and the amount of whitening agent in the compositions ranges from 0.01% to about 40% by weight of the substance. Water is also included in the compositions and comprises 0.1% to 95% by weight of the substance. The amount of substance applied on the strip is less than 0.2 grams/cm<sup>2</sup> (200 mm/cm<sup>2</sup>). The amount of substance applied to the strip of material or teeth will depend upon the size and capacity of the piece of material, concentration of the active, and the desired benefit (col. 7, lines 47-56). The strip is covered with a release liner (col. 9, lines 56-65). The mention of the release liner leads one to believe the strips are packaged products, therefore encompassing the instant claims.

Art Unit: 1614

The reference differs from the instant claims insofar as it does not disclose a mixture of polyvinyl alcohol and polyethylene oxide as a gelling agent to use with the whitening agent.

It would have been obvious to one of ordinary skill in the art to have placed a certain amount of whitening substance on the supporting layer of the primary reference motivated by the desire to provide an effective amount of whitening agent to the teeth to obtain the desired benefit and effect as disclosed by the secondary reference.

It would also have been obvious to one of ordinary skill in the art to have packaged the compositions of the primary reference motivated by the desire to protect the delivery systems, as disclosed by the secondary reference.

2) Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godbey et al (US 2002/0187181) in view of Sagel et al. (US 5,891,453) in further view of Xu et al. (US 2002/0187111).

The primary and secondary references, Godbey et al. and Sagel et al., are discussed above. The references differ from the instant claims insofar as they do not disclose the molecular weights of the polyethylene oxide polymers that may be used in the whitening compositions.

Xu et al. teach whitening strips comprising polyethylene oxide. The whitening agents include hydrogen peroxide (paragraph 0011). The ethylene oxide polymer comprises 50 to 95% of the composition (paragraph 0012). The polymer is hydratable and varying the properties of the polymer can control the release of the whitening agent.

Art Unit: 1614

Varying film thickness and using a mixture of different molecular weight polyethylene oxide polymers (100,000 –1,500,000 Daltons) varies the properties of the films (paragraph 0008-0010). Mixtures of polymers with different molecular weights are also disclosed by the primary reference. The strips are packaged in a suitable container (paragraph 0022). The reference differs from the instant claims insofar as it does not disclose a second polymer such as polyvinyl alcohol.

It would have been obvious to one of ordinary skill in the art to have used the polyethylene oxides of different molecular weights and mixtures as the polyoxyalkylenes in the compositions of the primary and secondary references motivated by the desire to make a whitening composition that provides a good balance of cohesive strength, is hydratable and has the desired rate of release of a whitening agent, as disclosed by the tertiary reference.

#### **Obvious-Type Double Patenting (Previous Rejection)**

Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of copending Application No. 10/820,590. The rejection is maintained in regards to claims 1-3 and 5-12.

Applicant argues the two applications are not the same. Applicant is prepared to file a Terminal Disclaimer upon notice of allowable subject matter.

Claims 1-3 and 5-12 are rejected.


Claims 13-16 are withdrawn.

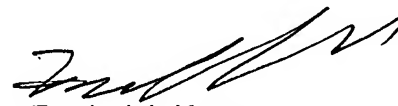
No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Lezah Roberts  
Patent Examiner  
Art Unit 1614

  
Frederick Krass  
Primary Examiner  
Art Unit 1614